

CHAPTER 1

COOPERATION WITH OTHER AGENCIES

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1.1 MEMORANDUM OF UNDERSTANDING 1/

The Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the Federal Grain Inspection Service (FGIS), Grain Inspection, Packers and Stockyards Administration, Department of Agriculture, have certain related objectives in carrying out their respective regulatory and service functions. In order to assure the most effective discharge of their responsibilities and that their activities are fully responsive to the public interest, the two agencies entered into a Memorandum of Understanding (MOU) concerning the inspection and grading of various products or commodities.

- a. Purpose. FGIS Program Directive 906.2, Implementation of the FGIS-FDA Memorandum of Understanding, sets forth the working arrangements between FGIS and FDA regarding their respective responsibilities in the inspection and standardization of grain, rice, pulses, and food products.
- b. Statutes Relating to the Agreement.
 - (1) FDA enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (Act). In fulfilling its responsibilities under the Act, FDA ensures that foods, including animal feed, are safe and wholesome and are labeled in a truthful, informative manner. FDA accomplishes this, in part, by inspecting facilities that process, hold, and distribute grain, rice, pulses, and similar food. FDA also examines samples of inspected food to determine whether the food is adulterated or misbranded within the meaning of the Act. FDA also promulgates, under the Act, standards of identity, quality, and fill of container for food products.
 - (2) FGIS, under the authority of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) (AMA) and the regulations thereunder (7 CFR Part 868), performs voluntary inspection and weighing services, upon request, to aid in the efficient marketing of agricultural products.
- 1/ This agreement applies only to those commodities assigned to FGIS by the Secretary of Agriculture.
- c. Services. Services include developing specifications and standards; providing

inspection, grading, and weighing services; and issuing certificates of quantity, quality, and condition to producers, processors, shippers, buyers, and other interested parties.

1.2 FDA RESPONSIBILITIES

During inspection of a facility that processes, packs, or holds agricultural products, FDA may:

- a. Request the FGIS inspector/licensee stationed at a facility to accompany the FDA inspector during the inspection. The FDA inspector and the FGIS inspector/licensee will discuss any conditions that they believe may result in violations of the Federal Food, Drug, and Cosmetic Act.
- b. Request FGIS to furnish information concerning quality determinations of specific lots of products against which FDA has taken or may take action. When involved in such an action, FDA will consider the results of official FGIS inspections and other available data, provided the information is relevant to the current condition of the product and the nature of the violation charged.

When an FDA action is to be based on an analysis by the FGIS inspector/licensee and FDA has not received the results of an appeal analysis, FDA through its appropriate field office will contact the designated FGIS field liaison person, confirm that an appeal analysis is being conducted, and request an oral report of the results of the analysis as soon as possible.

- c. Notify FGIS concerning details of objectionable conditions found to exist in processing plants, packing plants, grain elevators, or any other facilities where FGIS provides official services.
- d. Notify FGIS of the criteria FDA uses to determine when FDA should consider action under the Act against an agricultural product. Notification will ensure that FGIS does not classify an objectionable commodity as acceptable.
- e. Upon request of FGIS, review for possible conflict with the misbranding provisions of the Act the labels, legends, stamps, and other marks on products that are packed under the various official services.

1.3 FGIS RESPONSIBILITIES

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When performing functions under the AMA and regulations administered by FGIS that relate to agricultural products, FGIS will:

- a. Promptly notify FDA of the facilities that are subject to withholding of service, termination of contract, or denial of official FGIS services because of insanitary conditions or other processing deficiencies. Notification is not necessary if the plant management is cooperating in correcting the insanitary condition(s).
- b. Investigate any report from FDA that a processor, packer, merchandiser, or facility operator using official FGIS services has not corrected objectionable conditions found by FDA. Upon completion of the investigation, initiate appropriate action and notify FDA of the action taken.
- c. Refuse to inspect products which have been seized by FDA or which are known to be involved in formal FDA actions. This does not preclude official retest and appeal of authorized samples if the FDA action involves products which have been officially inspected.
- d. Promptly report to FDA the results of any inspection or analysis (including results of any appeal analysis, when available) for any product that may be actionable under the Act. Report to the appropriate FDA field office by telephone within 24 hours of the receipt of information that a specific lot of product is considered adulterated or in noncompliance by reason of failing to comply with FDA requirements. Immediately follow up with written notification using the appropriate format (see attachment).
- e. Furnish FDA, upon request, any pertinent information concerning the grade or quality of FGIS inspected specific lots of products against which FDA has taken or may take action.

1.4 MUTUAL AGREEMENTS

It is mutually agreed that:

- a. Field liaison will be maintained between FDA district offices and FGIS designated field persons. General matters involving the MOU may be referred to the agencies' liaison officers.
- b. Proposed regulations initiated by either agency which affect, establish, or amend food standards or other products covered by the MOU will be referred to the other agency for review and comment before the proposed regulations are published for broader comment.
- c. Both agencies will cooperate with industries in improving sanitation and food handling practices in processing plants, packing plants, or other facilities.
- d. Both agencies will exchange data and cooperate in developing sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products officially inspected.
- e. In order to avoid duplication of effort and to keep the disruption of plant operations to a minimum, inspection personnel shall cooperate with Federal, State, and local agencies performing comparable sanitation inspection services.
- f. Where feasible, before performing a sanitation inspection, inspection personnel should inquire of plant management as to when the plant last received a sanitation inspection. If another agency performed a sanitation inspection within the past 3 months, contact that agency and request a copy of their inspection report. Review the report and determine if there were any problem sanitation areas. Inquire of plant management as to the action taken to correct the problems and make a general observation of the problem areas. If it appears that the problems still exist and that little, if any, effort has been made to correct the problems, then make a thorough examination and conduct a complete sanitation inspection of the plant. If it has been more than 3 months since the last sanitation inspection, or if the agency performing the inspection will not supply a copy of the inspection report, make a complete sanitation inspection.

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g. Name and addresses of liaison officers:

(1) For the Food and Drug Administration:

Director, Field Programs
Center for Food Safety and Applied
Nutrition (HFS-600)
200 C Street, S.W.
Washington, D.C. 20204
202-205-4187

(2) For the Grain Inspection, Packers and Stockyards
Administration, Federal Grain Inspection Service:

Director, Field Management Division
Federal Grain Inspection Service
STOP 3630, Room 1641-S
Washington, D.C. 20090-3630
202-720-0228

It is FGIS policy that if any dispute arises concerning an interpretation as to an insanitary condition(s) in a plant, FDA shall be requested to examine the condition(s) in dispute and advise FGIS as to whether or not an insanitary condition(s) exists. FDA's decision is final and FGIS will be guided accordingly. If FDA is unable to make an examination, upon request, FGIS' decision is final.

If a Federal, State, or local agency requests that an FGIS inspector accompany and assist them in making a sanitation inspection of a plant, the inspector shall cooperate whenever and wherever possible.

ATTACHMENT
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(Date)

TO: FDA Field Office

FROM: FGIS Field Office Manager
FGIS Field Office

SUBJECT: Confirmation of Telephone Report

This will confirm our telephone report of (date) about the following inferior commodity lot of (product):

Commodity:

Contract No:

Car No:

Lot No:

Sampling Date:

Mill:

Location:

Amount:

Destination:

Contamination
per 50 grams:

Other Conditions: